L-30262-10

materialise
innovators you can count on

enovis™

Instructions for Use
Match Point System®
Guide and Model

materialise.com

Materialise USA LLC. I Helm Court 44650 I Plymouth MI I USA I service.enovis@materialise.com I materialise.com

This document contains general instructions for use for polyamide Match Point System guide and model. For case specific details please refer to the Case Report.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Match Point System guide

Device description / Performance characteristics

The Match Point System guide is a patient-matched device designed to fit on the patient's anatomy to transfer a patient-specific pre-operative plan to the OR. It is intended for surgical interventions in orthopedic procedures for total and reverse shoulder arthroplasty in skeletally mature patients.

Common name

Patient Specific Instrumentation (PSI) for shoulder arthroplasty

Indications for use

The Match Point System guide is intended to be used as a surgical instrument to assist in the intraoperative positioning of glenoid components used with total and reverse shoulder arthroplasty by referencing anatomic landmarks of the shoulder that are identifiable on preoperative CT-imaging scans.

The Match Point System guide can be used in conjunction with Enovis' following total and reverse shoulder implant systems and their respective compatible components: Reverse® Shoulder Prosthesis (K051075, K111629, K092873), Turon® Shoulder System (K080402), AltiVate™ Anatomic Shoulder System (K162024), AltiVate™ Anatomic Augmented Glenoid (K213387, K222592) and Altivate™ Reverse Glenoid (K233481).

The Match Point System guide is for single use only.
The Match Point System guide is intended for adult patients.
The Match Point System guide is to be used by a physician trained in the performance of surgery.

Material

Polyamide

Contraindications

Patients with conditions or diseases that affect bony landmark recognition.

The SurgiCase Shoulder Planner may restrict use for the Match Point System guide when placement of the pilot wire is not optimal for implant placement. To ensure safety and effectiveness of the Match Point System guide, the SurgiCase Shoulder Planner restricts the placement of the pilot wire within the intersection of two cones – a 45° cone from the neutral axis and a 60° cone from the normal of the glenoid face.

Any active infection of the surgical area where the surgery will be performed is a contraindication for Match Point System guide.

Storage and handling

The Match Point System guide must be stored in a clean and dry atmosphere, at ambient temperature and protected from sunlight and heat sources. Avoid exposing the guide to UV-light. Only open the package right before preparing the guide for surgery (i.e. before cleaning and sterilization).

CT, MRI and CBCT conditionality

N/A: no ferromagnetic components are present in the guide; the guide is not intended to be implanted. The Match Point System guide has not been evaluated for safety or compatibility in the CT or MR environment. It has not been tested for heating or image artifact creation. The safety of the Match Point System guide in the CT or MR environment is unknown.

Corresponding software

The pre-operative plan can be consulted in the SurgiCase Shoulder Planner.

Warnings

- If the device cannot be used for any reason, the surgeon should be prepared to use conventional instrumentation to perform the procedure.
- The user should be aware of possible allergic reactions to materials used in the guide. The patient should be informed on this matter by the user.
- The user should consult the instructions for use and surgical technique of respective implant system and their compatible components for the indications, warnings, precautions, adverse effects and contra-indications.
- Do not alter the guide from its original shape. Debris from the alteration could contaminate the operating region. In addition, altering the size of the guide may lead to an improper fit on the patient's anatomy.
- Do not use the guide if full surface contact is not achieved between the guide and the underlying patient's anatomy. Pressure must be placed on the guide according to the push direction to maintain contact during use. Loss of contact between the guide and the underlying anatomy may result in improper pilot wire position.
- The Match Point System guide is to be used by a physician trained in the performance of surgery.
- The guide should be properly cleaned before sterilization. Do not use if the guide is broken, cracked, or is visibly contaminated or if the stainless steel tubes (if present) are not tightly secured.
- The guide in this package is provided non-sterile. The guide in this package must be sterilized prior to use.
- Do not drop the guide. If a guide is dropped during surgery, it should be carefully inspected for any damage. If no visible damage is observed, the device can be reused after full reprocessing, i.e. cleaning and sterilization following the provided instructions in this document.

Single use

- This is a patient-matched, single use, disposable guide.
- Do not attempt to reuse or recondition the guide.
- Be aware that this patient-matched guide has been manufactured based on CT scans of the patient. If the patient's anatomy has changed significantly since the time of the CT-scan, the guide should not be used.
- Reuse of the guide could pose, for example, the following risks:
  - incorrect transfer of pre-operative plan due to unstable fit of the guide;
  - patient exposure to chemicals, particles, bacterial matter and/or endotoxins;
  - infections due to the unclean guide.
- The guide is intended exclusively for the patient for whom it is designed and manufactured. Do not use the guide for another patient.

Disposal

A single-use device (including a guide) that has been contaminated with blood, tissue or other bodily fluids/matter is considered infectious medical device waste and should be handled and disposed in accordance with hospital procedures.

Precautions

- Do not apply excessive force on the guide or place heavy objects on top.
- Markings on the guide used for indicating anatomical references and case information must be legible. These include lines indicating anatomical directions, identifiers with case information such as case identifier (see below). Notify your Materialise representative if the markings are not legible or if the identifiers do not correspond to the intended patient or surgeon.
- Use by date: even though the performances and characteristics of the plastic device are deemed not to be affected by the passage of time, it is required to use the Match Point System guide within 6 months from the date of performing the CT scans on which it is based.

If the patient's anatomy has changed significantly since the time of the CT-scan, the Match Point System guide should not be used, even if the time period of 6 months is not expired.

Patient specific guide identifiers

An identifier is indicated on each guide. This alphanumeric code links the guide unambiguously to the patient case. Each patient case is accompanied with a Content of the Box form and a Case Report, which specify all delivered surgical instruments, together with their identifier and a graphical illustration.

Before using the guide, check the identifier for readability and confirm that it corresponds with the patient's identity.

Possible adverse effects

Infection following the surgical procedure. Introduction of foreign materials can result in an inflammatory response or allergic reaction.

Match Point System model

Device description / Performance characteristics

The Match Point System model is a patient-matched device designed to represent the patient's anatomy. It is intended for surgical interventions in orthopedic procedures for total and reverse shoulder arthroplasty in skeletally mature patients.

Common name

Patient Specific Instrumentation (PSI) for shoulder arthroplasty

Indications for use

The Match Point System model is intended to be used as a surgical instrument to assist in the intraoperative positioning of glenoid components used with total and reverse shoulder arthroplasty by referencing anatomic landmarks of the shoulder that are identifiable on preoperative CT-imaging scans.

The Match Point System model can be used in conjunction with Enovis' following total and reverse shoulder implant systems and their respective compatible components: Reverse® Shoulder Prosthesis (K051075, K111629, K092873), Turon® Shoulder System (K080402), AltiVate™ Anatomic Shoulder System (K162024), AltiVate™ Anatomic Augmented Glenoid (K213387, K222592) and Altivate™ Reverse Glenoid (K233481).

The Match Point System model is for single use only.
The Match Point System model is intended for adult patients.
The Match Point System model is to be used by a physician trained in the performance of surgery.

Material

Polyamide

Contraindications

The SurgiCase Shoulder Planner may restrict use for the Match Point System model when placement of the pilot wire is not optimal for implant placement. To ensure safety and effectiveness of the Match Point System model, the SurgiCase Shoulder Planner restricts the placement of the pilot wire within the intersection of two cones – a 45° cone from the neutral axis and a 60° cone from the normal of the glenoid face.

Any active infection of the surgical area where the surgery will be performed is a contraindication for Match Point System model.

Storage and handling

The Match Point System model must be stored in a clean and dry atmosphere, an ambient temperature and protected from sunlight and heat sources. Avoid exposing the model to UV-light. Only open the package right before preparing the model for surgery (i.e. before cleaning and sterilization).

CT, MRI and CBCT conditionality

N/A: no ferromagnetic components are present in the model; the model is not intended to be implanted. The Match Point System model has not been evaluated for safety or compatibility in the CT or MR environment. It has not been tested for heating or image artifact creation. The safety of the Match Point System model in the CT or MR environment is unknown.

Corresponding software

The pre-operative plan can be consulted in the SurgiCase Shoulder Planner.

Warnings

- **Please note:** The 3D model visualized in the planning software and report may deviate slightly from the printed model, if ordered, since the printed model may still be refined further for guide design.
- The user should be aware of possible allergic reactions to materials used in the model. The patient should be informed on this matter by the user.
- Do not alter the model from its original shape. Debris from the alteration could contaminate the operating region.
- The Match Point System model is to be used by a physician trained in the performance of surgery.
- The model should be properly cleaned before sterilization.
- The model in this package is provided non-sterile. The model in this package must be sterilized prior to use.
- Do not drop the model. A model that is dropped during surgery should not be used anymore. The benefit of using the model may not outweigh the risk associated with prolonging the surgery by re-sterilization. Therefore, it is recommended that if a model is contaminated, the surgery proceeds without the aid of the model.

Single use

- This is a patient-matched, single use, disposable model.
- Do not attempt to reuse or recondition the model.
- Be aware that this patient-matched model has been manufactured based on CT scans of the patient. If the patient's anatomy has changed significantly since the time of the CT-scan, the model should not be used.
- Reuse of the model could pose, for example, the following risks:
  - incorrect transfer of pre-operative plan;
  - patient exposure to chemicals, particles, bacterial matter and/or endotoxins;
  - infections due to the unclean model.
- The model is intended exclusively for the patient for whom it is designed and manufactured. Do not use the model for another patient.

Disposal

A single-use device (including a model) that has been contaminated with blood, tissue or other bodily fluids/matter is considered infectious medical device waste and should be handled and disposed in accordance with hospital procedures.

Precautions

- Markings on the model used for indicating anatomical references and case information must be legible. These include identifiers with case information such as case identifier (see below). Notify your Materialise representative if the markings are not legible or if the identifiers do not correspond to the intended patient or surgeon.
- Use by date: even though the performances and characteristics of the plastic device are deemed not to be affected by the passage of time, it is advised to use the model within 6 months from the date of performing the CT scans on which it is based. If the patient's anatomy has changed significantly since the time of the CT-scan, the model should not be used, even if the time period of 6 months is not expired.

Patient specific model identifiers

An identifier is indicated on each model. This alphanumeric code links the model unambiguously to the patient case. Each patient case is accompanied with a Content of the Box form and a Case Report, which specify all delivered surgical instruments, together with their identifier and a graphical illustration.

Before using the model, check the identifier for readability and confirm that it corresponds with the patient's identity.

Possible adverse effects

Infection following the surgical procedure. Introduction of foreign materials can result in an inflammatory response or allergic reaction.

Match Point System guide and model

Technique for device placement

For case specific details consult the case planning report for the approved position and any additional comments regarding the use of the guide before use intraoperatively.

Every surgeon should be familiar with the surgical technique and the case-specific details prior to the surgery.

Fitting of the guide

- The guide is designed to fit the patient's glenoid anatomy. The fitting surface on the glenoid face and coracoid neck should be cleared of loose soft tissue and dried as much as possible to assure good fit of the guide.
- Do not remove osteophytes or alter the glenoid bony anatomy before fitting the guide.
- Do not damage the bony surface where the guide makes contact with the patient's glenoid anatomy.
- Do not remove cartilage.
- Compare the fit and position of the guide on the bone model to the planned fit and position on the patient's glenoid anatomy. The guide's fit and position on the bone model should match its fit and position on the patient's glenoid anatomy.
- Verify that full surface contact is achieved between the guide and the underlying glenoid anatomy with the exception of the 2 mm offset over the superior glenoid ridge. Check for gaps between the guide and the glenoid anatomy to ensure a proper fit.
- If it is not possible to place the guide on the patient in a stable position, the guide does not guarantee an accurate transfer of the pre-operative planning.
- Even in a stable position, it is possible that the guide does not make full contact with the bone over its entire surface, since it is not always possible to solve all of the undercuts. The undercuts depend on the shape of the patient's anatomy. During the design of the guide the amount of undercut is kept to a minimum to ensure a maximal contact between the fitting surface and guide.

Guided drilling

- Verify that the correct drill bit diameter is being used which corresponds to the guide drill cylinder diameter.
- Do not intend to modify the drill direction by drilling through the drill cylinder's surface.
- Apply and maintain pressure on the guide to keep contact between the guide surface and underlying patient anatomy during drilling.
- Remove the Match Point System. The guide can slide over the central glenoid pin. Take care not to alter the direction of the central glenoid pin while removing the guide.

Recommended cleaning instructions prior to sterilization

The Match Point System guide and model are NOT STERILE and must be thoroughly cleaned and sterilized prior to use.

The guide and the model can be cleaned using either manual or automated cleaning in a washer/disinfector (which fulfills the requirement of ISO 15883). Products must be removed from their original packaging before cleaning. A detergent intended for cleaning medical devices should be used, this can either be an alkaline detergent (with a pH 7-11, like TEC WASH III), or a neutral enzymatic cleaner (like Enzol).

As the device is single use, it should not come in contact with blood prior to (re)cleaning. However, in the case that blood is present on the device, the guide and the model cannot be (re)cleaned using the end user cleaning and they may no longer be used in surgery. The guide and the model may be processed up to two (2) times prior to use.

Manual cleaning

1. Rinse under cold running tap water for a minimum of 2 minutes.
2. Immerse the device in a freshly made detergent solution (in accordance with manufacturer's recommendations for the correct exposure time (with a minimum of 2 min), temperature, water quality and concentration). While cleaning use a soft bristled brush.
3. Remove the device from the detergent solution and rinse under cold running tap water for at least 2 minutes. While rinsing, use a syringe to flush the lumens of the device.
4. Repeat the immersion of the device with freshly made detergent solution and let it soak for 2 min. While cleaning use a soft bristled brush.
5. Remove the device from the detergent solution and rinse under running RO/ DI water for a minimum of 3 minutes. While rinsing, use a syringe to flush the lumens of the device.
6. Visually inspect the device for visible soil.
7. Perform a final rinse under running RO/DI water for a minimum of 1 minute.
8. Dry the guide and the model using a clean, lint-free cloth and/or filtered pressurized air.
9. Carefully examine the device to see if it is visually clean and undamaged.

Automated cleaning (with manual precleaning)

1. Rinse the device under cold running tap water for a minimum of 1 minute.
2. Rinse the device under RO/DI water for a minimum of 2 minutes. While rinsing, use a syringe to flush the lumens of the device.
3. Immerse the device in a freshly made detergent solution (in accordance with the manufacturer's recommendations for the correct exposure time (with a minimum of 1min), temperature, water quality and concentration). While immersed, use a soft bristled brush.
4. Remove the device from the detergent solution and rinse under cold running tap water for at least 1min. While rinsing, use a syringe to flush the lumens of the device.
5. Visually inspect the device for visual soil.
6. Transfer the device to the automated washer for processing. Select the cycle and ensure the following set of parameters is properly programmed:

Phase	Minimum duration (min)	Minimum temperature
1. Pre-Wash	02:00	Cold tap water
2. Wash (use detergent)	02:00	109.4°F (43°C)
3. Neutralize (*) (only to be performed when recommended per detergent instructions for use)	per detergent instructions for use	Warm tap water with neutralizer
4. Rinse	03:00	109.4°F (43°C)
5. Thermal disinfection (*)	01:00	194°F (90°C)
6. Drying	30:00 (**)	194°F (90°C)

(*) validated as non critical parameter for cleaning
(**) Critical (verified) parameter is ≥15min.

7. Carefully examine the device to see if it is visually clean and undamaged.

Recommended sterilization specifications

The guide and the model **must undergo sterilization** by the user in order to render it sterile prior to surgery. Remove the device from the original packaging. Sterilize the device using **pre-vacuum steam sterilization** in a sterilizer fulfilling the requirements of ISO 17665 series before use. The guide and the model can be sterilized up to two (2) times prior to use. Do not use a flash auto-clave cycle. The guide and the model are intended for single use only. Users should conduct testing in the health care facility to ensure that conditions essential to sterilization can be achieved. It is the user's responsibility to use the validated processing steps as given in the instructions below. During sterilization of single devices, pouches may be used. Only legally marketed, medical grade and validated sterilization pouches that are FDA approved should be used by the end-user for packaging the devices during sterilization. Ensure that the pouch is large enough to contain the devices without stressing the seals or tearing the pouch.

The steam sterilization settings used must fall within the following parameters to achieve a 10^{-6} sterility assurance level (SAL):

- Pre-vacuum Cycle [1]:
  Minimum temperature: 270°F (132°C)
  Minimum exposure time[2,3]: 4 minutes
  Minimum vacuum drying time: 30 minutes

Contact details

For any questions or concerns, please contact your Materialise representative or the Materialise customer service.

Comments or changes regarding the use of this device can be directed to attention of:

Materialise USA LLC.
44650 Helm Court
Plymouth
MI 48170
Tel: 734-259-7017
Fax: 734-662-7891

Patent Notice

This product is covered by the following patents:

EP2577978 (BE, CH, DE, FR, GB, NL), EP2670314 (DE, DK, FR, GB, LU, NL, SE), EP2770920 (BE, CH, DE, FR, GB), EP2775943 (BE, CH, DE, FR, GB, BE), BE1021299, AU2012328382, AU2012311521, US8,984,731, US9,289,221, US9,421,021, US10,010,334, US10,052,114

Manufacturer information

Manufactured by:
Materialise NV
Technologielaan 15
3001 Leuven
BELGIUM

Distributed by:
Enovis
9800 Metric Blvd.
Austin, TX 78758
U.S.A.

[1] In the case local or national specifications for steam sterilization requirements are stricter or more conservative than those listed in this table, please contact Materialise before sterilizing and using the guide and the model.
[2] Validated minimum exposure time at the minimum steam sterilization temperature required to achieve a 10^{-6} sterility assurance level (SAL).
[3] AAMI/AORN steam sterilization cycles with longer exposure times than the one listed are also acceptable as long as a maximum exposure time of 18 minutes is not exceeded.

Symbol legend

Symbol	Title	Description
	Patient number	Indicates a unique number associated with an individual patient.
	Manufacturer	Indicates the medical device manufacturer.
	Distributor	Indicates the entity distributing the medical device into the locale.
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Do not re-use	Indicates a medical device that is intended for one single use only.
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Use by date	Indicates the date after which the medical device is not to be used.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Quantity	Quantity of the sold unit, not the number of parts in the sold unit.
	Medical device	Indicates the item is a medical device.
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	Prescription only	CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician

This is version 10 of the document and has been issued in September 2024.

materialise
innovators you can count on

materialise
innovators you can count on