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Instructions for Use
Polyamide Match Point
System[®] guides and
models

This document contains general instructions for use for polyamide Match Point System® guides and models. For case-specific instructions please refer to the Case Report.

Device description

Match Point System® guides and models are custom-made devices per European definition, designed to fit or represent the patient's anatomy. They are intended for surgical interventions in orthopaedic procedures for total and reverse shoulder arthroplasty.

Common name: patient specific instrumentation for shoulder arthroplasty

Indications for use

The Match Point System® 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® can be used in conjunction with DJO's following total and reverse shoulder implant systems and their respective compatible components: the Reverse® Shoulder Prosthesis (K051075, K111629, K092873, K112069), the Turon® Shoulder System (K080402, K123982), and the AltiVate™ Anatomic Shoulder System (K162024).

The Match Point System® guide is single use only.

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® when placement of the drill bit is not optimal for implant placement. To ensure safety and effectiveness of the Match Point System® guides, the SurgiCase Shoulder Planner restricts the placement of the drill bit 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® guides.

Warnings

- If the device is unable to 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 or model. 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.
- These are patient-specific, single use, disposable guides and models.
- Do not attempt to reuse or recondition the guides or models.
- Do not alter the guides or models from their 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 drill bit position.
- Match Point System® guides are to be used by a trained physician in the performance of surgery.
- Be aware that these patient-specific guides and models have 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 guides or models should not be used.
- The guides and models should be properly cleaned before sterilization. Do not use if the guides are broken, cracked, or are visibly contaminated or if the stainless steel tubes (if present) are not tightly secured.
- The guides and models in this package are provided non-sterile. The guides and models in this package must be sterilized prior to use.

Precautions

- It is advised to use the guide or model within 6 months after performing the CT scans on which they are based. If the patient's anatomy has changed significantly since the time of the CT-scan, the guide or model should not be used, even if the time period of 6 months is not expired.
- Do not apply excessive force on the guides or place heavy objects on top.
- Markings on guides 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.

Patient specific guide identifiers

An identifier is indicated on each guide and model. 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.

Instructions for use

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

Fitting of the guide

- The guide is designed to fit the patient anatomy. The fitting surface on the glenoid face and coracoid neck should be cleared of loose soft tissue 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.
- Compare the fit position of the guide to the planned fit position. The fitting position on the bone model should match the fitting position on the patient's anatomy.
- 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's drill cylinder diameter.
- Do not intend to modify the drill direction by drilling through the drill cylinder's surface.
- Verify full surface contact is achieved between the guide and the underlying patient anatomy with the exception of the 2mm offset over the superior glenoid ridge.
- Maintain pressure on the guide to keep contact between the guide surface and underlying patient anatomy during drilling.
- Remove the guide

Recommended cleaning instructions prior to sterilization

Match Point System® guides and models are **NOT STERILE** and must be thoroughly cleaned and sterilized prior to use

Manual cleaning cycle

1. Rinse the guides and models under cold running tap water to remove gross soil. Use a soft bristled brush to remove soil from the surface of the guides and models. Use a syringe to flush cylinders and slots.
2. Immerse the guides and models in an enzymatic detergent and allow them to soak for a minimum of 25 minutes. The detergent should be of neutral or near neutral pH (e.g. ELMA TEC CLEAN N1 detergent). Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
3. Remove the device from the enzyme solution and rinse in soft tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
4. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50kHz.
5. Rinse the device in purified water for at least 3 minutes or until there is no sign of soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
6. Repeat the sonication and rinse steps above.
7. Remove excess moisture from the device with a clean, absorbent and non-shedding wipe

Automated cleaning cycle

1. Pre-rinse the device and bone models under running tap water to remove gross soil. Use a soft bristled brush to remove soil from the surface of the device and bone models. Use a syringe and long, narrow, soft-bristled brush to flush cylinders and slots.
2. Wash the device and bone models using an automatic washer unit. It is recommended to use a detergent (like Enzol) as recommended by the manufacturer of the automatic washer unit.
3. Dry the guides and bone models with filtered pressurized air and/or wipe with a soft lint-free cloth.

Cleaning cycle	Instructions
Pre-rinse	1 minute minimum 30°C (86°F) - 80°C (176°F) Running tap water, clean with tools
Pre-wash	2 minutes 30°C (86°F) - 80°C (176°F)
Enzyme wash	None
Wash 1	4 to 10 minutes at 60°C (140°F) - 80°C (176°F)
Rinse 1 (1-4)	None
Thermal Rinse	None
Pure water Rinse	2 minute minimum at 40°C (104°F) - 80°C (176°F)

Sterilization

Recommended sterilization specifications

The guides can be sterilized twice prior to use. The guides 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.

Sterilize the guides or models using [pre-vacuum steam sterilization](#) before use.

During sterilization of single devices, pouches may be used. Only legally marketed, FDA cleared and validated sterilization pouches should be used by the end-user for packaging the devices during sterilization.

Use one of the following standard steam sterilization settings:

Pre-vacuum Cycle UK, NL^{1,2}

- Minimum temperature: 134°C (273.2°F)
- Maximum temperature: 137°C (278.6°F)
- Minimum exposure time: 3 minutes
- Maximum exposure time: 18 minutes
- Minimum vacuum drying time: 30 minutes

World Health Organization Prevacuum Cycle^{2,3}

- Minimum temperature: 134°C (273.2°F)
- Maximum temperature: 137°C (278.6°F)
- Minimum exposure time: 18 minutes
- Maximum exposure time: 18 minutes
- Minimum vacuum drying time: 30 minutes

Contact details

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

Comments or changes regarding the use of this device can be directed to attention of the manufacturer: Materialise N.V., Technologielaan 15, B-3001 Leuven, Belgium,

Tel.: +32 16 744 930, Fax: +32 16 744 60

- 1 Minimum validated steam sterilization temperature required to achieve a 10⁻⁶ sterility assurance level (SAL).
- 2 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 guides.
- 3 Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is concern regarding TSE/CJD contamination.