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# Instructions for Use Instruments with a Measuring Function

This instruction for use is not intended for distribution in the USA.

# Instructions for Use

Instruments with a Measuring Function facilitate the surgical procedure for implant devices.

This IFU covers surgical measuring devices for CMF, Spine and Trauma systems.

Important note for medical professionals and operating room staff: These Instructions for Use do not include all of the information necessary for selection and use of a device. Please read the instructions for use, the DePuy Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

## Materials

Aluminum – EN 573-3  
 PAEK – ISO 10993  
 PEEK – ASTM F2026  
 PSU – ISO 16061  
 Silicone Rubber – ASTM F 2042/F 2038  
 Stainless Steel – ISO 10088-1/ASTM F899  
 Ti Al6 V4 – ASTM B348 Gr 5

## Intended use

Instruments with a Measuring Function are intended to measure quantitatively an anatomical parameter of the human body.

## Indications/Contraindications

Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The indications/contraindications are based upon the implant devices rather than the instruments. Specific indications/contraindications for the Implants can be found in the respective Synthes implant instructions for use.

## Patient Target Group

Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The patient target group is based upon the implant devices rather than the instruments. Specific patient target group for the Implants can be found in the respective Synthes implant instructions for use.

## Intended User

This IFU alone does not provide sufficient background for direct use of the Device or System. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU, the surgical procedures, if applicable, and/or the Synthes "Important Information" brochure as appropriate.

Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

## Expected Clinical Benefits

Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The clinical benefits for the instruments are based upon the implant devices rather than the instruments. Specific clinical benefits for the implants can be found in the respective Synthes implant instructions for use.

## Performance Characteristics of the Device

Synthes has established the performance and safety of Instruments with a measuring function and that they represent state of the art medical devices for measuring quantitatively an anatomical parameter of the human body when used according to their instructions for use and labeling.

## Potential Adverse Events, Undesirable Side Effects and Residual Risks

Synthes manufactures surgical measuring instruments intended to prepare the site and aid in implantation of Synthes implants. The adverse events/side effects are based upon the implant devices rather than the instruments. Specific adverse events/side effects for the implants can be found in the respective implant Instructions For Use.

## Measuring Device

Measuring Devices are intended to measure quantitatively an anatomical parameter of the human body.

| Part                | Measuring range (mm)                  | Degree of Accuracy (mm) |
|---------------------|---------------------------------------|-------------------------|
| <b>Calipers</b>     |                                       |                         |
| 324.060             | 0–180                                 | ±0.2                    |
| 389.186             | 0–180                                 | ±0.2                    |
| 03.501.065          | 0–60                                  | ±0.5                    |
| 03.501.074          | 0–40                                  | ±0.5                    |
| 03.501.715          | 0–20                                  | ±0.5                    |
| <b>Depth Gauges</b> |                                       |                         |
| 319.003             | 0–25                                  | ±0.85                   |
| 319.004             | 0–30                                  | ±1.25                   |
| 319.005             | 0–43                                  | ±0.85                   |
| 319.006             | 0–50                                  | ±1.25                   |
| 319.010             | 0–60                                  | ±0.7                    |
| 319.011             | 0–110                                 | ±0.65                   |
| 319.060             | 0–40                                  | ±0.6                    |
| 319.090             | 4–110                                 | ±0.5                    |
| 319.091             | 10–150                                | ±1.1                    |
| 319.100             | 14–110                                | ±0.7                    |
| 319.110             | 0–24                                  | ±0.5                    |
| 319.520             | 0–44                                  | ±0.4                    |
| 319.530             | 0–44                                  | ±1                      |
| 323.040             | 18–114                                | ±0.8                    |
| 323.041             | Only used in conjunction with 323.040 |                         |
| 355.790             | 14–90                                 | ±0.45                   |
| 356.835             | 18–110                                | ±1.1                    |
| 357.402             | 12–110                                | ±0.8                    |
| 357.789             | 20–78                                 | ±0.85                   |
| 357.790             | 14–100                                | ±0.5                    |
| 357.790–EXS         | 14–100                                | ±0.5                    |
| 357.791             | 14–100                                | ±0.45                   |
| 387.292             | 0–50                                  | ±0.75                   |
| 03.010.019          | 18–110                                | ±1.1                    |
| 03.010.072          | 18–110                                | ±1.1                    |
| 03.010.428          | 18–110                                | ±1.1                    |
| 03.010.494          | 10–100                                | ±0.6                    |
| 03.019.017          | 20–98                                 | ±0.5                    |
| 03.019.029          | 20–98                                 | ±0.5                    |
| 03.025.052          | 20–110                                | ±1.1                    |
| 03.108.026          | 20–110                                | ±0.5                    |
| 03.113.028          | 10–100                                | ±0.9                    |
| 03.118.007          | 0–100                                 | ±0.9                    |
| 03.120.049          | 10–60                                 | ±0.6                    |
| 03.122.052          | 24–74                                 | ±0.15                   |
| 03.130.250          | 0–43                                  | ±0.6                    |
| 03.161.028          | 0–50                                  | ±0.75                   |
| 03.168.017          | 0–100                                 | ±1.1                    |
| 03.305.005          | 40–90                                 | ±0.95                   |
| 03.501.001          | 0–50                                  | ±1                      |
| 03.503.036          | 0–44                                  | ±1                      |
| 03.503.085          | 0–44                                  | ±0.5                    |
| 03.420.050          | 0–50                                  | ±0.6                    |
| 03.424.060          | 0–60                                  | ±0.6                    |
| 03.424.090          | 0–90                                  | ±0.7                    |
| 03.427.060          | 0–60                                  | ±0.6                    |
| 03.535.060          | 0–60                                  | ±0.6                    |
| 03.535.110          | 6–110                                 | ±0.6                    |
| 03.536.060          | 20–70                                 | ±0.15                   |

| Part                            | Measuring range (mm) | Degree of Accuracy (mm) |
|---------------------------------|----------------------|-------------------------|
| <b>Direct Measuring Devices</b> |                      |                         |
| 311.690                         | 40–150               | ±0.8                    |
| 311.690–EXS                     | 40–150               | ±0.8                    |
| 311.720                         | 70–120               | ±0.6                    |
| 319.150                         | 8–70                 | ±0.75                   |
| 319.155                         | 20–80                | ±0.75                   |
| 319.170                         | 20–80                | ±0.75                   |
| 319.210                         | 10–150               | ±0.95                   |
| 319.700                         | 30–180               | ±0.85                   |
| 319.701                         | 25–140               | ±1.1                    |
| 319.702                         | 8–50                 | ±0.95                   |
| 319.703                         | 0–40                 | ±0.9                    |
| 323.029                         | 6–32                 | ±0.4                    |
| 323.034                         | 6–32                 | ±0.5                    |
| 323.060                         | 10–60                | ±1.05                   |
| 323.061                         | 6–58                 | ±0.5                    |
| 324.037                         | 18–85                | ±4.1                    |
| 324.208                         | 0–140                | ±1.3                    |
| 338.050                         | 40–170               | ±1.15                   |
| 338.170                         | 40–150               | ±1                      |
| 338.329                         | 75–150               | ±0.9                    |
| 351.717                         | 160–480              | ±3.7                    |
| 356.829                         | 70–130               | ±1.4                    |
| 357.042                         | 60–125               | ±0.85                   |
| 357.385                         | 80–130               | ±1.9                    |
| 357.430                         | 70–150               | ±0.4                    |
| 358.698                         | 34–54                | ±1                      |
| 360.255                         | 160–340              | ±3.4                    |
| 387.550                         | 28–50                | ±1.5                    |
| 03.631.521                      | 25–100               | ±1.483                  |
| 03.010.083                      | 40–100               | ±1.55                   |
| 03.010.085                      | 40–130               | ±0.85                   |
| 03.010.090                      | 34–54                | ±0.6                    |
| 03.010.106                      | 18–100               | ±1                      |
| 03.010.429                      | 18–100               | ±0.8                    |
| 03.010.492                      | 40–100               | ±1.55                   |
| 03.010.493                      | 40–130               | ±0.85                   |
| 03.037.020                      | 70–130               | ±0.9                    |
| 03.037.027                      | 70–130               | ±0.4                    |
| 03.037.036                      | 240–480              | ±3.7                    |
| 03.045.035                      | 160–480              | ±3.7                    |
| 03.108.003                      | 10–80                | ±2.1                    |
| 03.108.037                      | 10–50                | ±1.3                    |
| 03.110.000                      | 10–30                | ±0.9                    |
| 03.110.006                      | 0–40                 | ±1                      |
| 03.111.000                      | 0–30                 | ±0.3                    |
| 03.111.005                      | 0–40                 | ±0.6                    |
| 03.168.003                      | 50–140               | ±0.8                    |
| 03.207.004                      | 35–184               | ±0.8                    |
| 03.226.002                      | 5–40                 | ±0.95                   |
| 03.226.008                      | 10–40                | ±1.1                    |
| 03.226.030                      | 18–110               | ±0.75                   |
| 03.227.030                      | 30–160               | ±0.75                   |

| Part                                | Measuring range (mm) | Degree of Accuracy (mm) |
|-------------------------------------|----------------------|-------------------------|
| <b>Osteotomy Correction Devices</b> |                      |                         |
| 395.000                             | 0–70/4°–20°          | ±0.41/4°                |
| 395.001                             | 5–16                 | ±0.9                    |
| 03.108.008                          | 0–100                | ±0.1                    |
| 03.108.039                          | 0–100                | ±0.1                    |
| 03.211.009                          | 1.5–7                | ±0.3                    |
| <b>Reduction Instruments</b>        |                      |                         |
| 313.354                             | 0–70                 | ±1.2                    |
| 399.003                             | 0–30                 | ±0.5                    |
| <b>Rulers</b>                       |                      |                         |
| 333.370                             | 0–180                | ±0.1                    |
| 03.401.083                          | 0–250                | ±0.1                    |
| <b>Height Measuring Devices</b>     |                      |                         |
| 324.092                             | 0–120                | ±1.5                    |
| 03.661.010                          | 20–150               | ±0.45                   |

#### Warnings and Precautions

Measuring devices may be used to measure various anatomical parameters in the human body and in the measurement of various implantable medical devices. Device specific precautions and warnings related to measuring devices are described in the corresponding Instructions for Use for those specific implantable devices.

Health care professionals should be qualified by appropriate training in the use of measuring devices. Measurement error can potentially result in implant failure from selecting the wrong size of implant.

Measured parameters are only valid where measuring devices are processed and maintained per Synthes "Important Information".

Take care to avoid damaging the nerve and vessel bundles, soft tissue and organs present in the human body where measuring devices are being used to measure an anatomical parameter.

These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed.

#### Combination of medical devices

Synthes has not assessed compatibility with devices provided by other manufacturers and assumes no liability in such instances.

#### Treatment before device is used

Synthes measuring devices supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".



Non-Sterile

#### Troubleshooting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

**Clinical Processing of the Device**

Detailed instructions for reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

**Disposal**

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Not all products are currently available in all markets.

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Synthes GmbH  
Eimattstrasse 3  
4436 Oberdorf  
Switzerland  
Tel: +41 61 965 61 11  
[www.jnjmedicaldevices.com](http://www.jnjmedicaldevices.com)