Instructions for Use
Instruments with a Measuring Function

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

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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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
PPSU – 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)
Calipers		
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
Depth Gauges		
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)
Direct Measuring Devices		
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
03.231.017	25–145	±1,6

Part	Measuring range (mm)	Degree of Accuracy (mm)
Osteotomy Correction Devices		
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
Reduction Instruments		
313.354	0–70	±1.2
399.003	0–30	±0.5
Rulers		
333.370	0–180	±0.1
03.401.083	0–250	±0.1
Height Measuring Devices		
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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