IFU *Arthro*Save KneeReviver

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CE

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ENGLISH - Important Medical Information

PRE-OPERATIVE PRECAUTIONS

This package insert includes information on basic precautions and (re)processing instructions for the *Arthro*Save KneeReviver. Please consult the applicable surgical technique for selection and use of a device and check the full labelling for other essential information. Surgical Technique brochures may be requested from the distributor *ArthroSave*. Ensure use of the most recent Surgical Technique by contacting the distributor.

The *Arthro*Save KneeReviver can only be used by surgeons who are fully familiar with the surgical technique and who have been instructed to this end. The responsible surgeon must take care not to use the instruments to exert inappropriate stress on the patient and must scrupulously comply with the operating procedures as described in the applicable surgical technique.

The surgeon should strictly follow the recommendations in the surgical technique. All staff involved should be familiar with the surgical procedures associated with the knee joint distraction technique to avoid adversely affecting device performance or surgical outcome.

To reduce the risk of damage, care must be taken not to distort the implants or nick, hit or score them with the instruments. Extreme care must be taken when the devices are used near vulnerable structures including nerves and blood vessels.

CONTACT

Please contact your *Arthro*Save representative for questions and comments regarding the application of the product that are not covered in this IFU or the surgical technique.
See contact information at the top of this document.

MANUFACTURER

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PROCESSING CATEGORIES

The *ArthroSave* KneeReviver system consists of three trays: 1) the *ArthroSave* KneeReviver, 2) the *ArthroSave* KneeReviver Toolbox and 3) the *ArthroSave* KneeReviver pre-drilling Toolbox. The trays can be provided separately by the distributor. The trays are illustrated in the appendices.

***ArthroSave* KneeReviver**

The *ArthroSave* KneeReviver tray contains all the components of the KneeReviver that will be attached to the patient for the duration of the treatment.

REF	Part	Quantity
AS14	KneeReviver Tray	1
AS1	Distractor left	1
AS3	Tibial block left	1
AS2	Distractor right	1
AS4	Tibial block right	1
AS8	Half pin locking bolt	10

***ArthroSave* KneeReviver Toolbox**

The ArthroSave KneeReviver Toolbox tray contains reusable surgical instruments and single use implants.

Reusable surgical instruments:

REF	Part	Quantity
AS15 or AS16	KneeReviver Toolbox Tray	1
AS5	Trocar ø 5 mm	2
AS6	Half pin guiding sleeve ø 5 mm	2
AS7	Sleeve guiding bolt	4
AS9	Torque limiter 13 Nm	1
AS10	Hexagonal bit	1
AS11	Hexagonal box spanner bit	1
AS12	Distraction key	1
AS13	Distance bush	1

Single use implants:

REF	Part	Quantity
14018.03.100	Self-drilling half pin 200x5mm[1]	10

[1] The Half pins 200x5mm are under CE mark of legal manufacturer MK Medical. They are available in the original packaging and with the original documentation. They are used within the intended purpose. BAAT Medical has verified that the Half pins are safe in use in combination with the ArthroSave instrumentation.

***ArthroSave* KneeReviver pre-drilling Toolbox**

The ArthroSave KneeReviver Toolbox tray contains reusable surgical instruments and single use implants.

Reusable surgical instruments:

REF	Part	Quantity
AS16	KneeReviver Toolbox Tray	1
AS5	Trocar ø 5 mm	2
AS6	Half pin guiding sleeve ø 5 mm	2
AS7	Sleeve guiding bolt	4
AS9	Torque limiter 13 Nm	1
AS10	Hexagonal bit	1
AS11	Hexagonal box spanner bit	1
AS12	Distraction key	1
AS13	Distance bush	1
AS17	Trocar ø 3.5 mm	2
AS18	Drill guiding sleeve ø 3.5 mm	2
AS19	T-handle keyless chuck	1
315.050	Drill bit ø 3.5 mm, 225/200 mm[2]	2

Single use implants:

REF	Part	Quantity
14018.03.101	Half pin 200x5mm[1]	10

OR

REF	Part	Quantity
294.560	Schanz Screw ø 5.0mm, L200/50mm[3]	10

[2] The Drill bit ø 3.5 mm is under CE mark of legal manufacturer DePuySynthes. They are available in the original packaging and with the original documentation. They are used within the intended purpose. BAAT Medical has verified that the Drill bits are safe in use in combination with the ArthroSave instrumentation.

[3] The Schanz Screw ø 5.0mm is under CE mark of legal manufacturer DePuySynthes. They are available in the original packaging and with the original documentation. They are used within the intended purpose. BAAT Medical has verified that the Schanz Screws are safe in use in combination with the ArthroSave instrumentation.

(RE) PROCESSING INSTRUCTIONS

See Appendix I for an overview of the reprocessing steps.

***ArthroSave* KneeReviver tray**
The *ArthroSave* KneeReviver can be provided sterile or non-sterile in consultation with the distributor.

In case the KneeReviver is provided sterile by the distributor, it will be provided with a declaration of sterilization (DoS). The tray is wrapped in a sterilization wrap and ready to use. Do not use the KneeReviver if there is any indication of non-sterility, e.g. visible damage to the sterile packaging. Store the KneeReviver in an appropriate environment until use.

In case the KneeReviver is provided non-sterile by the distributor, it will be provided with a declaration of decontamination (DoD). The KneeReviver must be cleaned and sterilized in the hospital CSSD according the instructions step 13-15 below.

The nature and complexity of the product requires training of the reprocessing procedure. For this reason, the KneeReviver must be reprocessed by an organization which has been trained by a product specialist from the distributor in the required processing steps. This organization can be part of a hospital or an external CSSD. Reprocessing includes all steps that are required to guarantee safe reuse.

In case of shipments between hospital and the external CSSD:
- The KneeReviver must be loaded in a shipping container defined by your *Arthro*Save representative.
- All the track and trace labels of the hospital must be removed.
- The KneeReviver must be shipped according instructions of the qualified reprocessing company.

1 Application procedure
Application must be performed by a trained surgeon according the instructions in the Surgical Technique.

2 Patient use
The patient wears the KneeReviver for a period of 6 weeks. The patient must follow the instructions provided by the surgeon according to the Surgical Technique.

3 Removal
The KneeReviver must be removed by a trained surgeon according to the Surgical technique. System components are placed back in the dedicated sterilization tray.

4 Cleaning and disinfection after use (optional)
The KneeReviver can be processed according the following cleaning and disinfection instructions immediately after the removal procedure. Cleaning and disinfection is only required if it will not be immediately reprocessed or if requested by the distributor. This procedure does not guarantee cleanliness of the device. Thorough cleaning is guaranteed by the qualified reprocessing step. Do not disassemble the KneeReviver:

- Machine washing with a detergent with a maximum pH value of 11
- Load the KneeReviver such that cannulations and holes can drain
- Run a disinfection cycle at 90°C for 5 minutes
- Rinse with demineralised water
- Dry the KneeReviver after cleaning; do not exceed 120 °C

5 Steam sterilization (optional)
Wrap the product in a sterilization wrap according to ISO 11607 / EN 868. This procedure does not guarantee sterility of the device. Do not disassemble the KneeReviver:

Method: Pre-vacuum dynamic air removal (EN 13060 / EN 285 / ISO 17665)
Temperature: 134 °C
Time: 3 min
Drying time: 20 min

6 Manual cleaning
See document: 14018ER170224_Workinstructions *Arthro*Save KneeReviver.

7 Disassembly
See document: 14018ER170224_Workinstructions *Arthro*Save KneeReviver.

8 Ultrasonic cleaning
See document: 14018ER170224_Workinstructions *Arthro*Save KneeReviver.

9 Cleaning and disinfection
See document: 14018ER170224_Workinstructions *Arthro*Save KneeReviver.

10 Inspection and revision
See document: 14018ER170224_Workinstructions *Arthro*Save KneeReviver.

11 Assembly and lubrication
See document: 14018ER170224_Workinstructions *Arthro*Save KneeReviver.

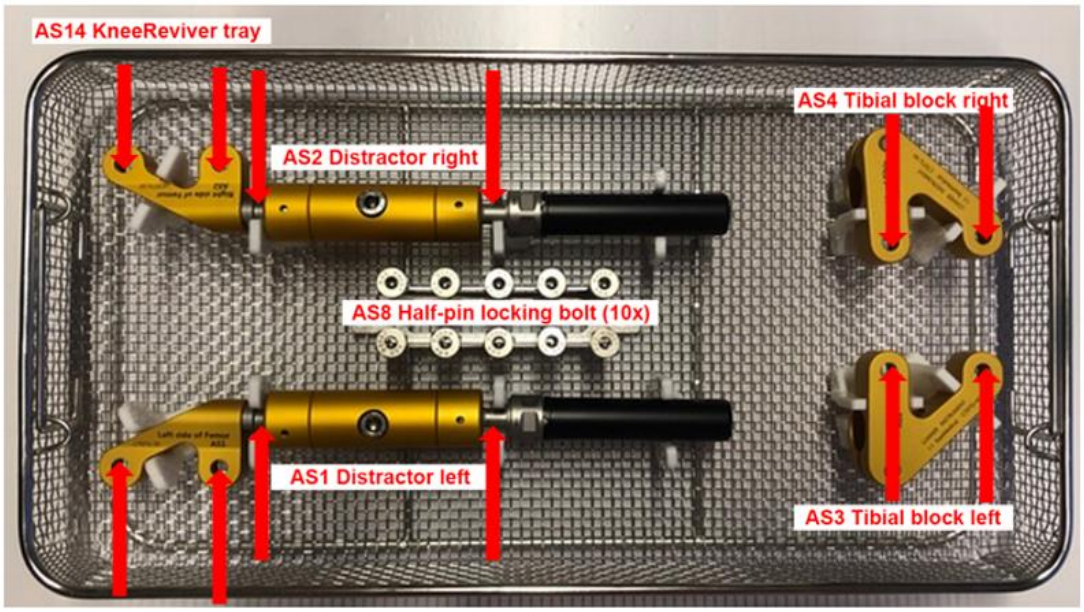
12 Steam sterilization
See document: 14018ER170224_Workinstructions *Arthro*Save KneeReviver.

Note: Steps 13-15 only need to be performed when you receive the KneeReviver non-sterile.

13 Cleaning and disinfection before use
Clean the tray in an automatic washer-disinfector (ISO 15883). Load the KneeReviver such that cannulations and holes can drain.

- Rinse 2 min (cold municipal water)
- Cleaning at 55 °C (± 2 °C) for 5 min with cleaning agent Neodisher MediClean forte (0.5 % v/v)
- Rinse 1 min (cold municipal water)
- Rinse 1 min (demineralized water)
- Thermal disinfection at 90 °C for 5 min (A_0-value > 3000)
- Drying at 110 ºC for 25 min

14 Lubrication
Lubricate the collet holes in the aluminum blocks (8x) and the ball joints (4x) with Neodisher IP spray. These positions are indicated with red arrows in the figure below.



15 Steam sterilization
Wrap the product in a sterilization wrap according to ISO 11607 / EN 868.

Method: Pre-vacuum dynamic air removal (EN 13060 / EN 285 / ISO 17665)
Temperature: 134 °C
Time: 3 min
Drying time: 20 min

***ArthroSave* KneeReviver Toolbox and KneeReviver pre-drilling Toolbox**
The *ArthroSave* KneeReviver (pre-drilling) Toolbox can be provided sterile or non-sterile in consultation with the distributor.

In case the KneeReviver (pre-drilling) Toolbox is provided sterile by the distributor, it will be provided with a declaration of sterilization (DoS). The tray is wrapped in a sterilization wrap and ready to use. Do not use the KneeReviver (pre-drilling) toolbox if there is any indication of non-sterility, e.g. visible damage to the sterile packaging. Store the KneeReviver (pre-drilling) toolbox in an appropriate environment until use.

In case the KneeReviver (pre-drilling) Toolbox is provided non-sterile by the distributor, it will be provided with a declaration of decontamination (DoD). The KneeReviver (pre-drilling) Toolbox must be cleaned and sterilized in the hospital CSSD according the instructions steps 10T-11T.

The nature and complexity of the product requires training of the reprocessing procedure. For this reason, the KneeReviver (pre-drilling) Toolbox must be reprocessed by an organization which has been trained by a product specialist from the distributor in the required processing steps. This organization can be part of a hospital or an external CSSD. Reprocessing includes all steps that are required to guarantee safe reuse.

In case of shipments between hospital and the external CSSD:
- The KneeReviver (pre-drilling) Toolbox must be loaded in a shipping container defined by your *ArthroSave* representative.
- All the track and trace labels of the hospital must be removed.
- The KneeReviver (pre-drilling) Toolbox must be shipped according instructions of the qualified reprocessing company.

1T Application procedure
The KneeReviver Toolbox or the KneeReviver pre-drilling Toolbox contains the instrument set for application of the *ArthroSave* KneeReviver. The Toolbox is not required for the removal procedure but can be used for this purpose.

2T Cleaning and disinfection (optional)
The KneeReviver can be processed according the following cleaning and disinfection instructions immediately after the procedure. Clean the tray in an automatic washer-disinfector (ISO 15883).

- Rinse 2 min (cold municipal water)
- Cleaning at 55 °C (± 2 °C) for 5 min with cleaning agent Neodisher MediClean forte (0.5 % v/v)
- Rinse 1 min (cold municipal water)
- Rinse 1 min (demineralized water)
- Thermal disinfection at 90 °C for 5 min (A_0-value > 3000)
- Drying at 110 °C for 25 min

3T Steam sterilization (optional)
Wrap the product in a sterilization wrap according to ISO 11607 / EN 868.

Method: Pre-vacuum dynamic air removal (EN 13060 / EN 285 / ISO 17665)
Temperature: 134 °C
Time: 3 min
Drying time: 20 min

4T Manual cleaning
See 14018ER170224_Workinstructions *Arthro*Save KneeReviver toolbox

5T Ultrasonic cleaning
See 14018ER170224_Workinstructions *Arthro*Save KneeReviver toolbox

6T Cleaning and disinfection
See 14018ER170224_Workinstructions *Arthro*Save KneeReviver toolbox

7T Inspection and revision
See 14018ER170224_Workinstructions *Arthro*Save KneeReviver toolbox

8T Refill single-use implants
See 14018ER170224_Workinstructions *Arthro*Save KneeReviver toolbox

9T Steam sterilization
See 14018ER170224_Workinstructions *Arthro*Save KneeReviver toolbox

Note: Steps 10T-11T only need to be performed when you receive the KneeReviver (pre-drilling) toolbox non-sterile.

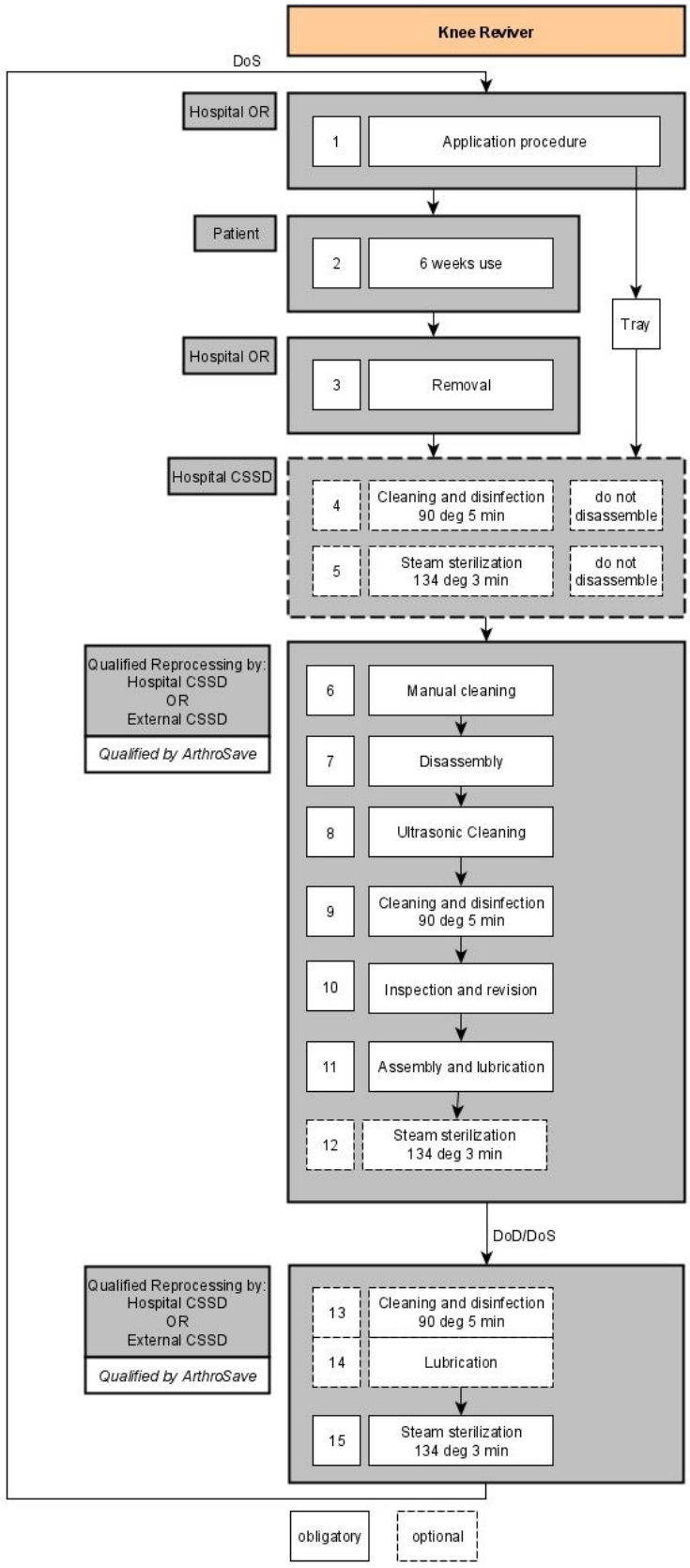
10T Cleaning and disinfection
The KneeReviver Toolbox and the KneeReviver pre-drilling Toolbox can be processed according the following cleaning and disinfection instructions immediately after the procedure. Clean the tray in an automatic washer-disinfector (ISO 15883). Load the KneeReviver such that cannulations and holes can drain.

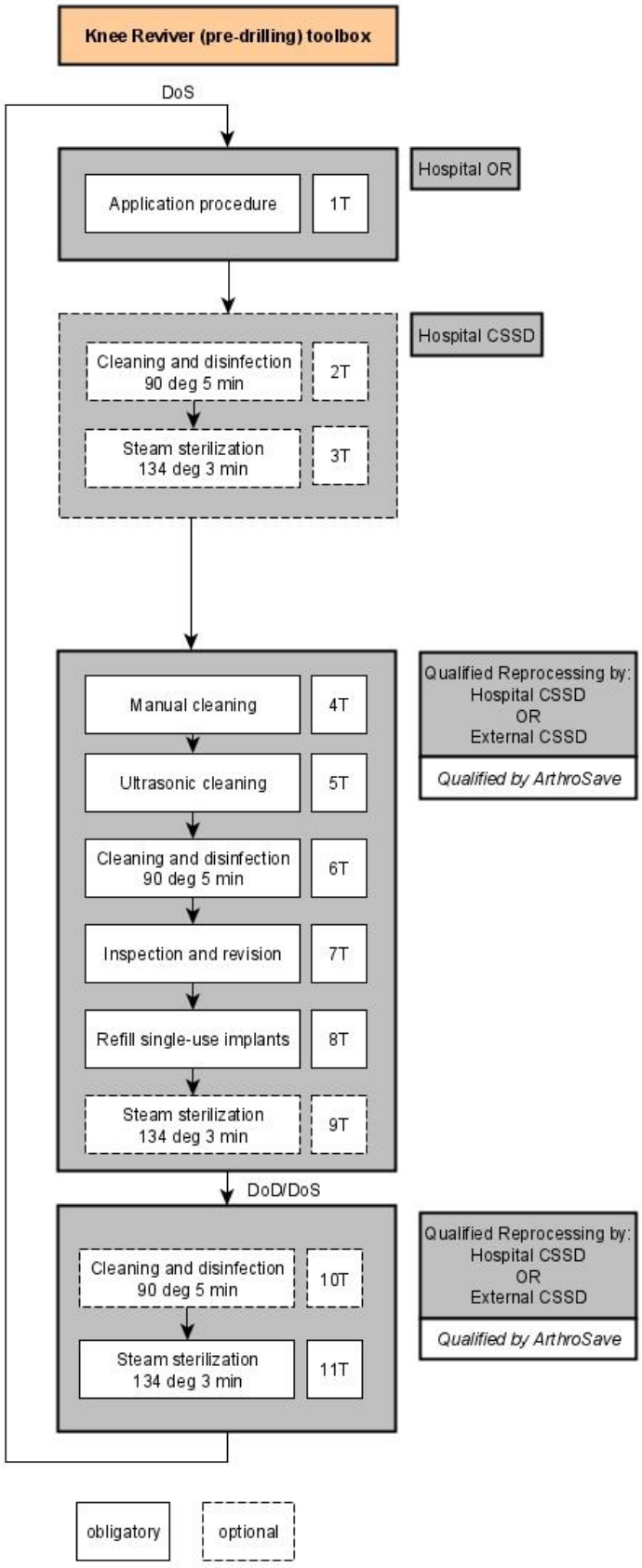
- Rinse 2 min (cold municipal water)
- Cleaning at 55 °C (± 2 °C) for 5 min with cleaning agent Neodisher MediClean forte (0.5 % v/v)
- Rinse 1 min (cold municipal water)
- Rinse 1 min (demineralized water)
- Thermal disinfection at 90 °C for 5 min (A_0-value > 3000)
- Drying at 110 °C for 25 min

11T Steam sterilization
Wrap the product in a sterilization wrap according to ISO 11607 / EN 868.

Method: Pre-vacuum dynamic air removal (EN 13060 / EN 285 / ISO 17665)
Temperature: 134 °C
Time: 3 min
Drying time: 20 min

APPENDIX I, Product lifecycle flowcharts




Knee Reviver (pre-drilling) toolbox
DoS
Application procedure
1T
Hospital OR
Cleaning and disinfection 90 deg 5 min
2T
Steam sterilization 134 deg 3 min
3T
Hospital CSSD
Manual cleaning
4T
Ultrasonic cleaning
5T
Cleaning and disinfection 90 deg 5 min
6T
Inspection and revision
7T
Refill single-use implants
8T
Steam sterilization 134 deg 3 min
9T
Qualified Reprocessing by: Hospital CSSD OR External CSSD
Qualified by ArthroSave
DoD/DoS
Cleaning and disinfection 90 deg 5 min
10T
Steam sterilization 134 deg 3 min
11T
Qualified Reprocessing by: Hospital CSSD OR External CSSD
Qualified by ArthroSave
obligatory
optional

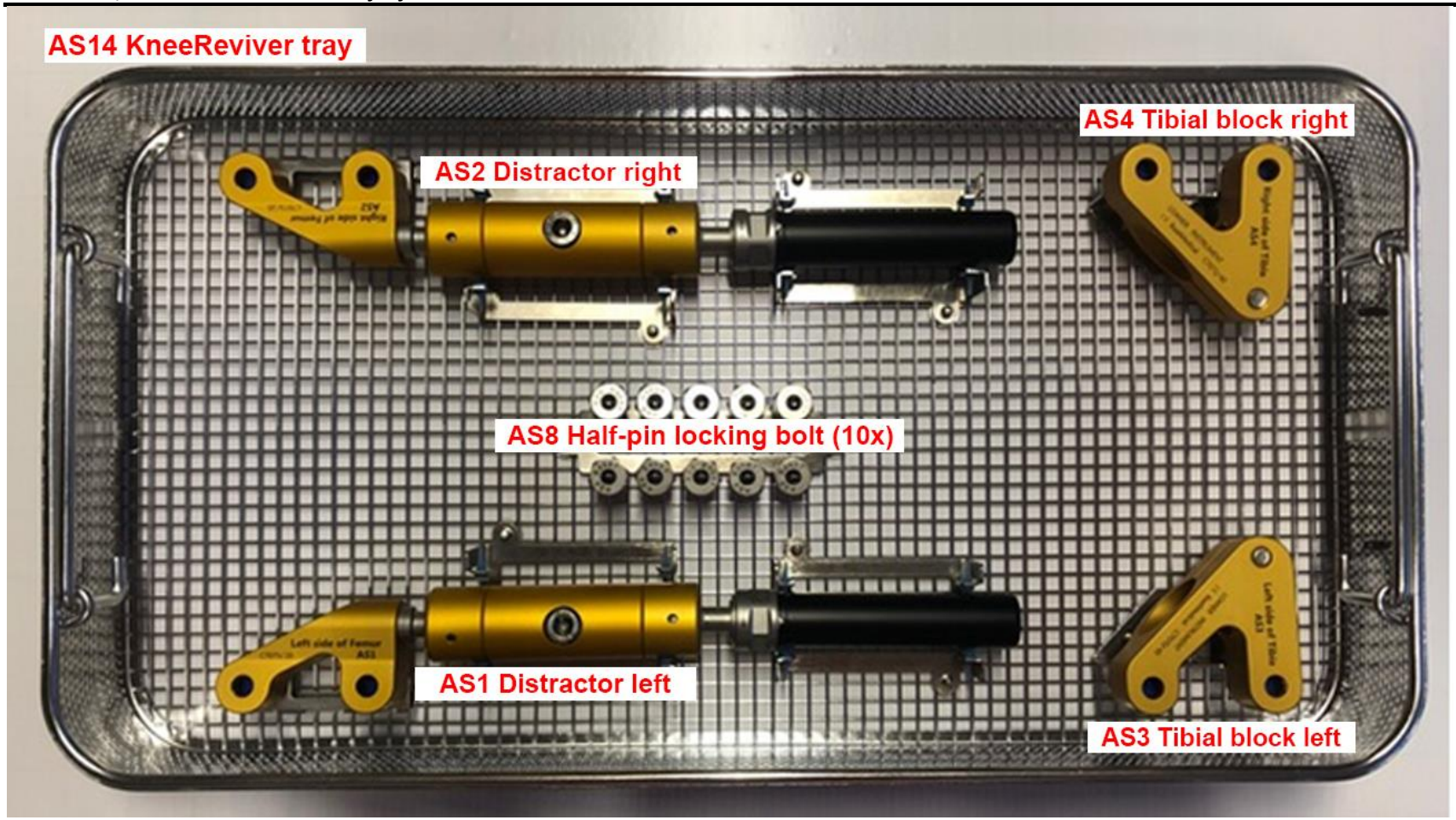


Figure 1 ArthroSave KneeReviver - variant 1

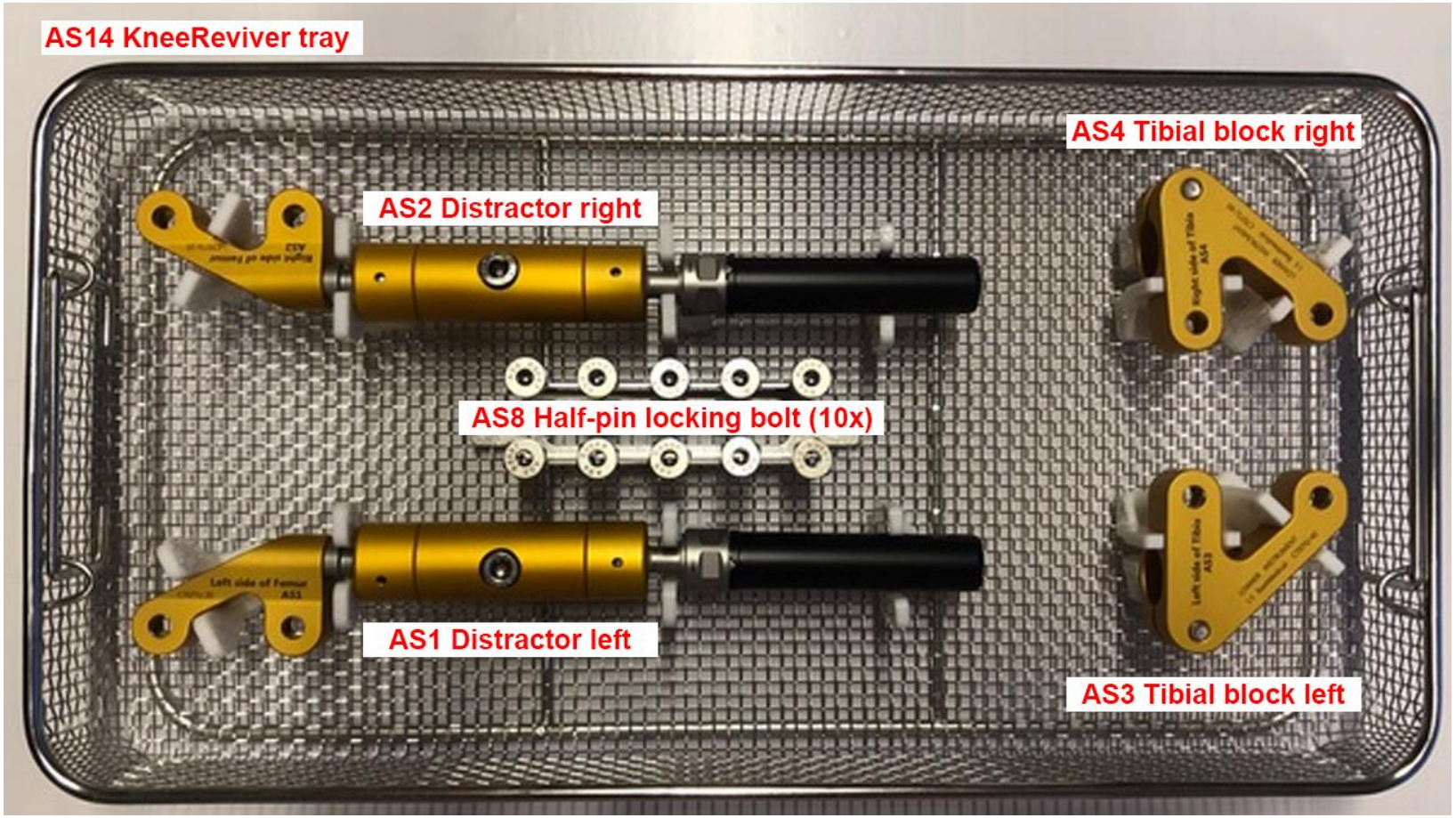


Figure 2 ArthroSave KneeReviver - variant 2

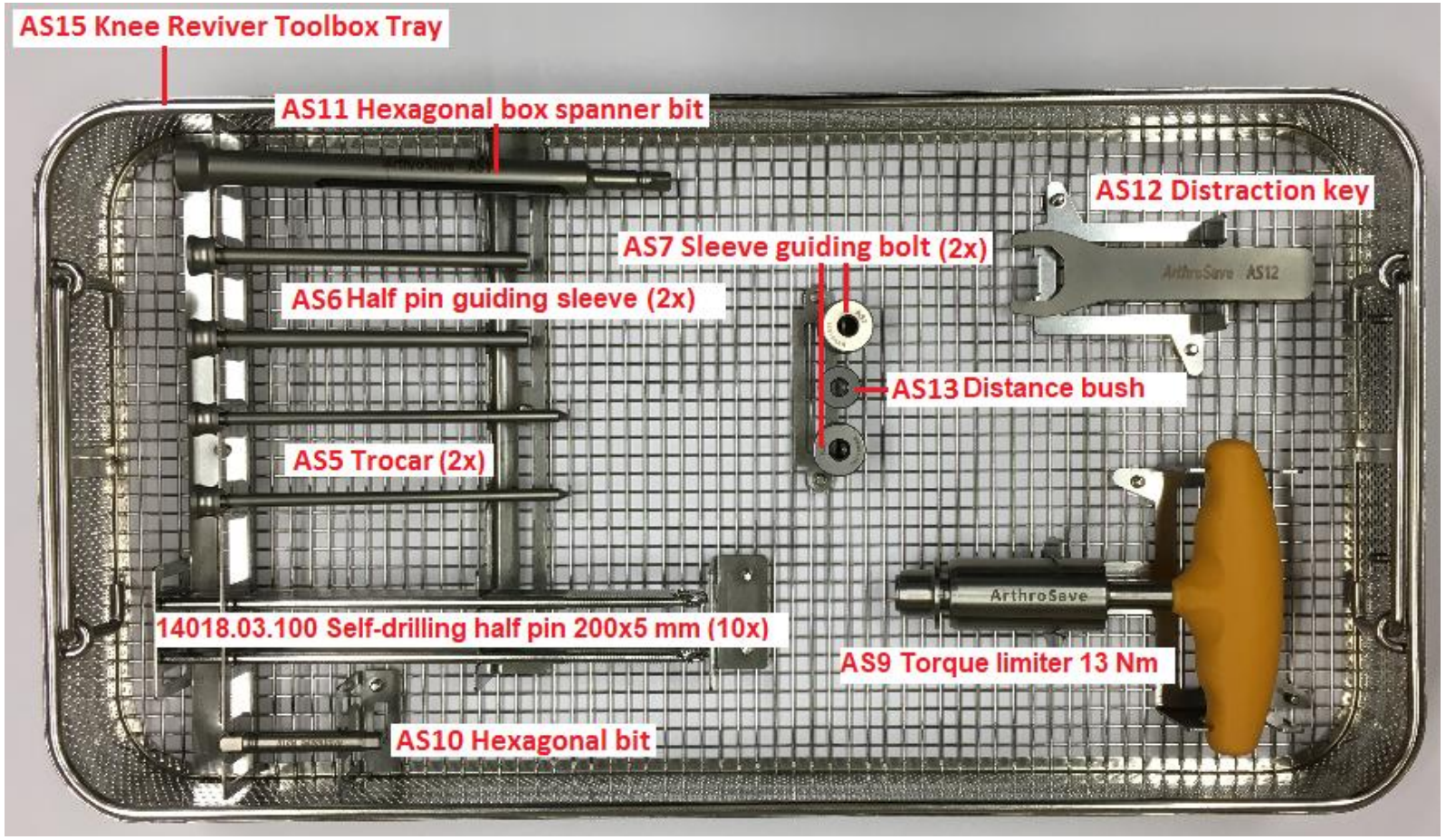


Figure 3 ArthroSave KneeReviver Toolbox - variant 1

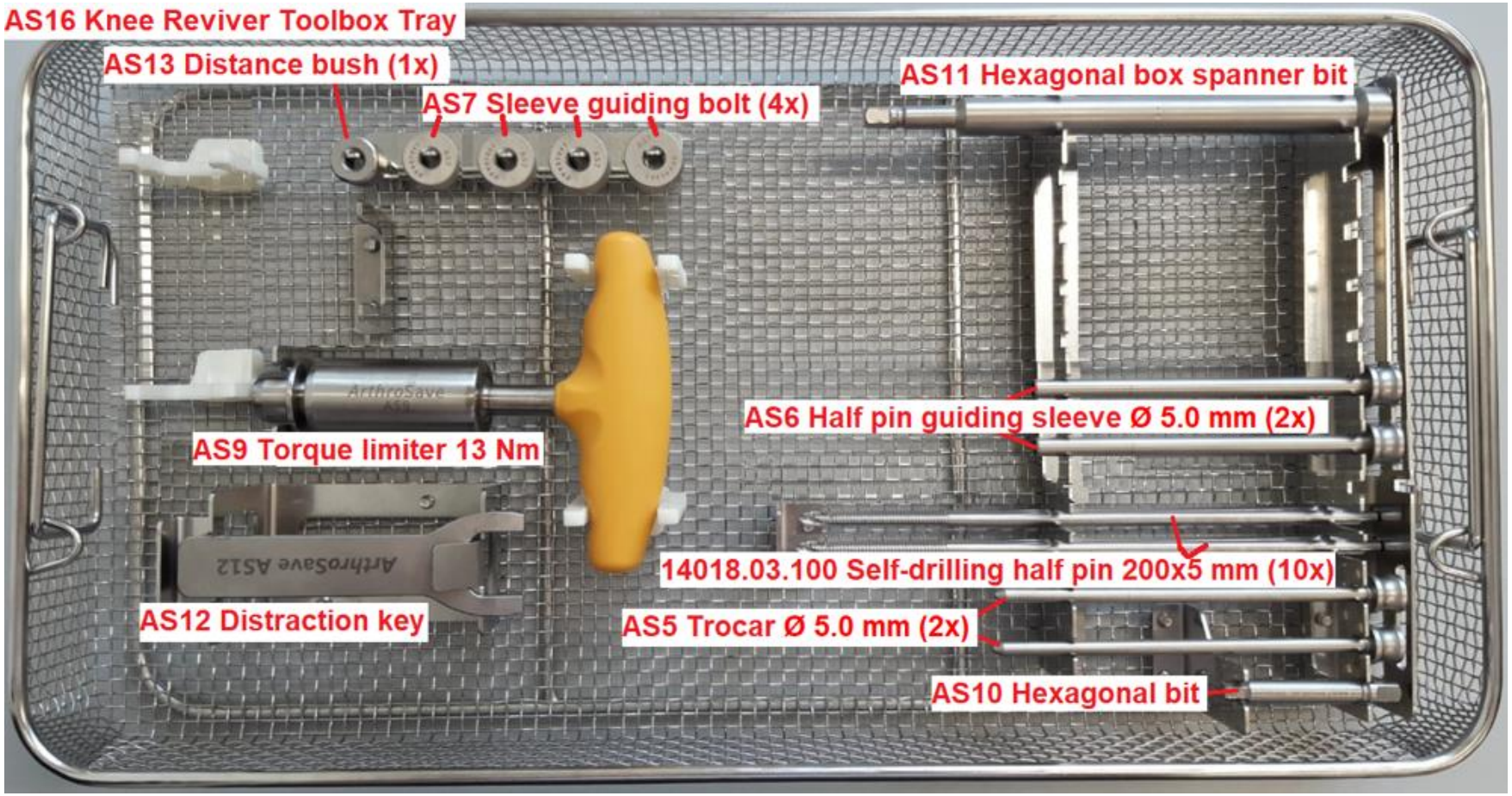


Figure 4 ArthroSave KneeReviver Toolbox – variant 2

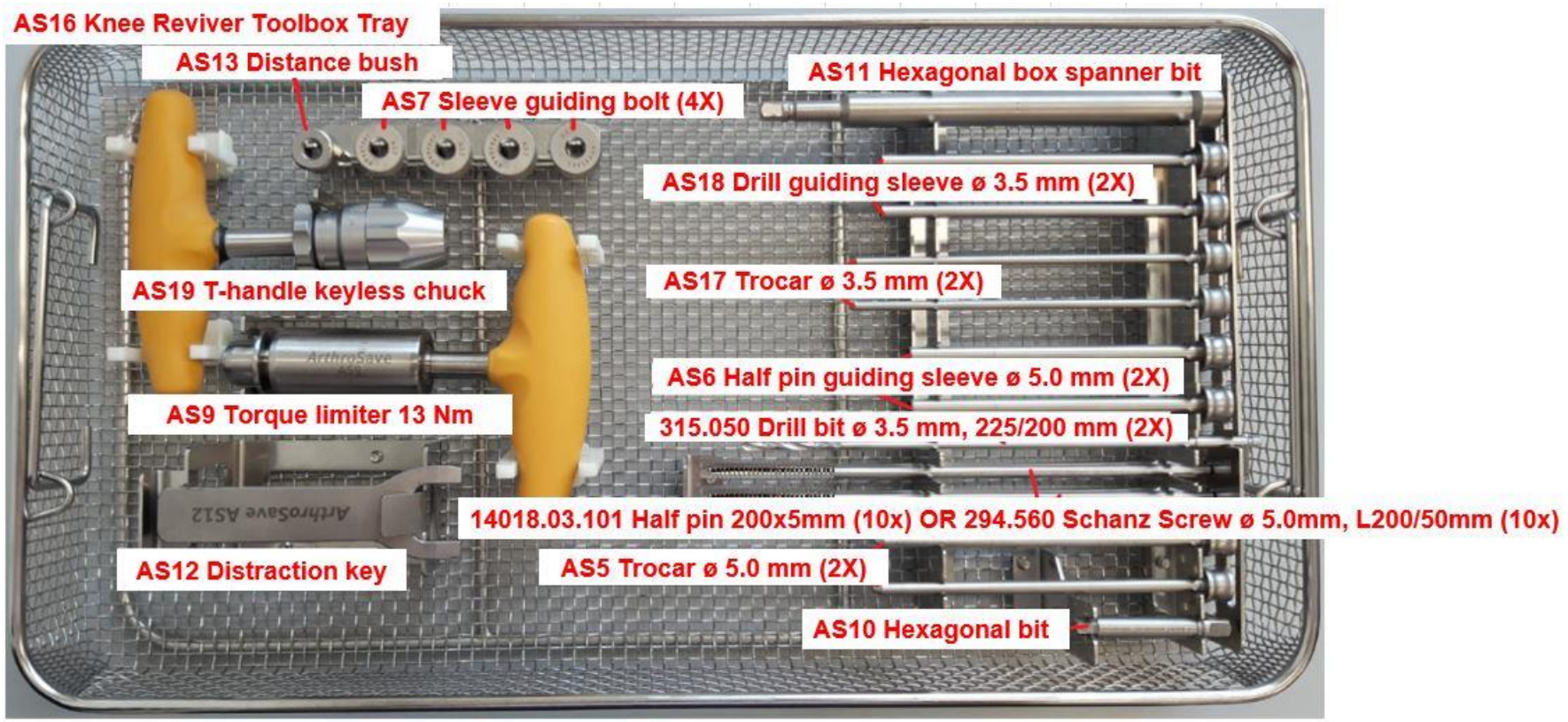


Figure 5 ArthroSave KneeReviver pre-drilling Toolbox