



# REPROCESSING OF ORTHOPAEDICS DEVICES



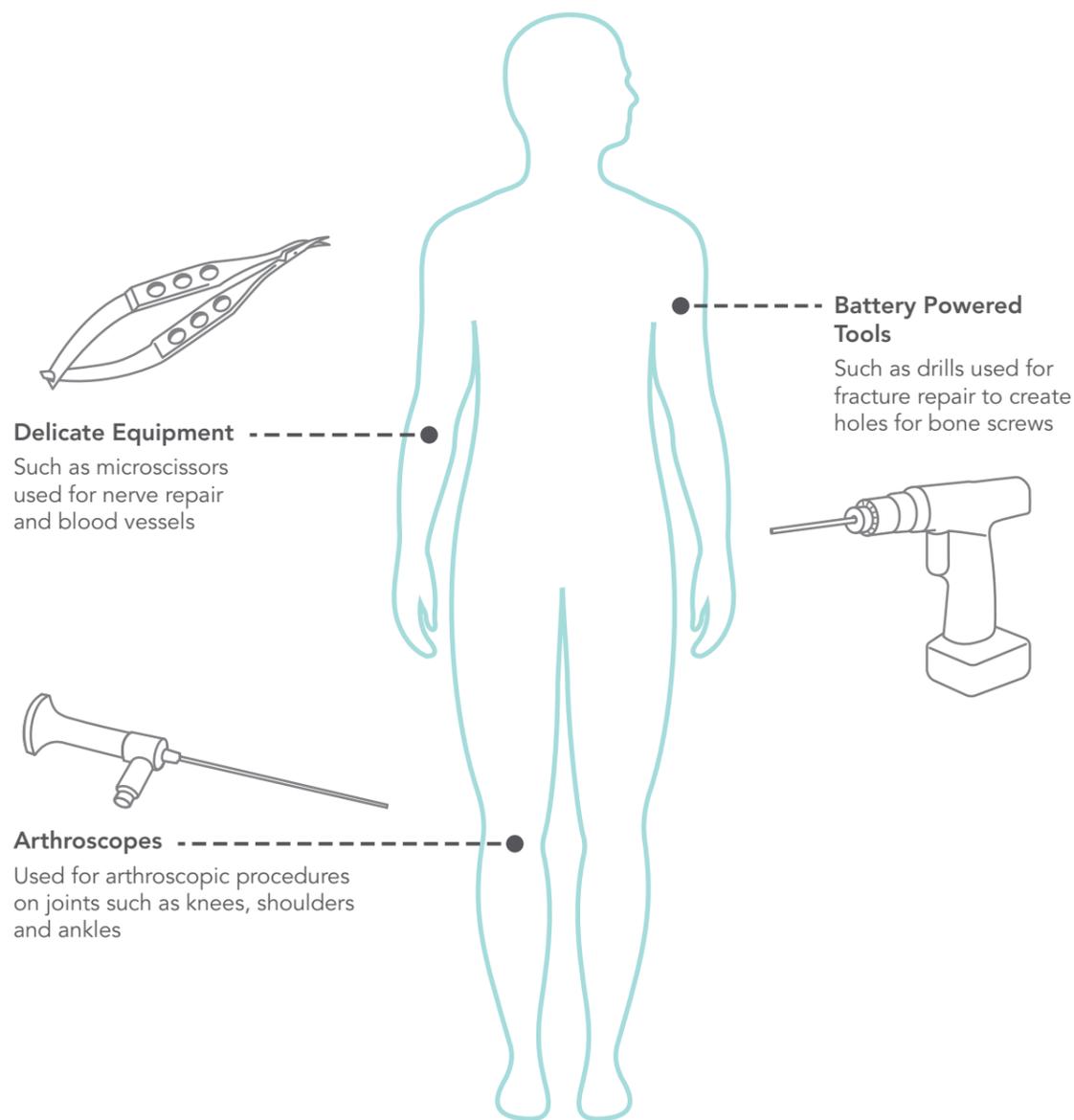
## Is It Time For A Change?

- Devices used in orthopaedic surgery are diverse but are all used critically, according to the Spaulding Classification,<sup>1</sup> and therefore must be reprocessed by sterilization; the most common method of which is steam sterilization.
- Steam sterilization can be problematic for orthopaedic devices due to the damage it can cause to batteries and delicate steel equipment, leading to risks to patient care and a high frequency of costly replacements.
- STERRAD® would provide the highest standard of patient care, offer a more convenient reprocessing method suitable for all orthopaedic devices, and can lead to financial benefits.

Orthopaedics describes the treatment of conditions of the musculoskeletal system, such as the bones, joints, ligaments, tendons, muscles and nerves.

Surgical procedures in this area are varied and most commonly include arthroplasty (joint replacements), arthroscopy (the minimally invasive technique for diagnosing and treating joint problems) and the repair of broken bones or damaged ligaments and muscles.

The diverse nature of orthopaedic procedures means that surgeons may require robust, powered mechanical tools and also a range of delicate steel instruments, depending on the procedure required.



### Device Reprocessing

Orthopaedic devices are used critically, as per the Spaulding Classification,<sup>1</sup> and must therefore be sterilized. Not all sterilization methods are suitable in orthopaedics, since they may damage devices or risk harm to patients or staff. Steam sterilization is typically used when reprocessing orthopaedic devices. However, the high heat and moisture used in this process presents a number of challenges.

### Challenges with High Temperature Steam Reprocessing

During steam sterilization, devices are typically exposed to moisture and high temperatures of 131–135°C, with direct steam contact required to ensure proper microbicidal activity.<sup>2</sup>

- Exposing batteries to these conditions for even very short periods can lead to a loss of charge, as well as reducing the battery lifetime by limiting maximum charge capacity.<sup>3</sup>
- This increases the risk of battery failure during surgery, which may cause disruptions and delays during the procedure.
- Battery failure may also lead to a high frequency of battery replacement at a great expense.
- Mishandling of orthopaedic devices when still wet after steam sterilization can be a source of re-contamination and infection.<sup>4</sup>

#### Case study

In one US hospital, the STERRAD® system resulted in only 2 battery replacements in a 9-month period compared to 34 replacements in the previous 6 months when steam sterilization was used. The estimated annual saving was USD 17,000.<sup>5</sup>



The harsh process of steam sterilization can also damage rigid scopes, such as arthroscopes, and delicate steel surgical equipment, particularly the fine tips and cutting blades of microsurgical devices used in some orthopaedic procedures. There are a number of consequences of this that may impact patient care:<sup>6</sup>

- Reduced longevity of arthroscopes and delicate surgical instruments leading to higher costs through additional repairs and earlier replacements.
- Devices that wear faster may show reduced performance until they can be repaired or replaced.
- Discovery of damaged equipment during surgery can lead to disruptions in the operating theatre.

#### Case study

After 30 reprocessing cycles of microsurgical scissors using steam or STERRAD®, the steam sterilized scissors demonstrated a noticeable drag in cutting whereas there was no loss of functionality caused by STERRAD® reprocessing.<sup>6</sup> The Orthopedics and Urology departments of Barmherzige Brueder Hospital found that sterilizing rigid scopes, such as arthroscopes, with STERRAD® instead of steam reduced their average repair costs by 33%.<sup>7</sup>



Careful thought needs to be given to alternative sterilization modalities, since not all methods are equally effective at removing all contaminants from orthopaedic devices and may increase the risk of outbreaks.

#### Case study: Knee joint sepsis following arthroscopic surgery

Knee infection after arthroscopic surgeries is a rare but devastating complication. The increasing popularity of the procedure means outbreaks have been reported in a number of facilities, with sterilization methods such as formaldehyde tablet gas sterilization being linked to these events.<sup>8,9</sup> A case series of 7 such incidents concluded that "more aggressive sterilization techniques should be utilized in operating rooms".<sup>9</sup>

## Benefits of STERRAD® for Low Temperature Sterilization

Given these challenges, there is a need for low temperature sterilization methods that are able to improve the longevity of batteries, arthroscopes and delicate steel equipment used in orthopaedic surgeries, whilst maintaining patient safety.

Two of the most established methods for low temperature sterilization are hydrogen peroxide gas plasma (STERRAD®) and ethylene oxide (EtO). The use of EtO, however, is expensive when considering the cost of protecting staff and patients, and has significant limitations:

EtO is extremely toxic and flammable, is a workplace hazard due to being classified as a human carcinogen, and may pose fire and explosion risks.<sup>2</sup>



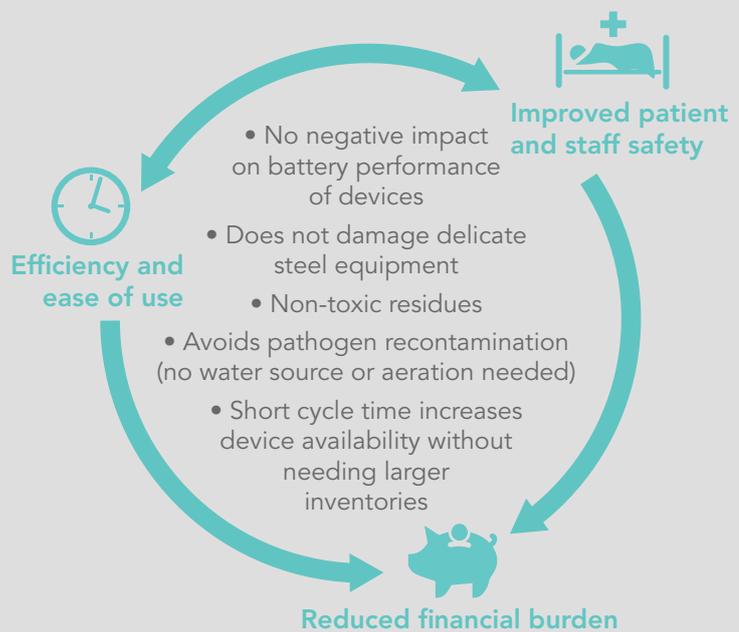
Very long cycle times may create the need to hold more devices in inventory to ensure that sterile devices are readily available, increasing instrument purchasing costs.



### Why Choose STERRAD®?

STERRAD® Systems sterilize orthopaedic devices safely and effectively, without the instrument damage associated with high temperature steam sterilization.

Reprocessing instruments using low-temperature hydrogen peroxide gas plasma with STERRAD® also avoids the safety and time issues of EtO sterilization, optimizing device reprocessing and the delivery of patient care. With hospitals reporting a 33% reduction in device repair costs compared to steam sterilization and up to USD 9,000 annual saving in water bills compared to EtO sterilization, the cost savings of using STERRAD are also clear.<sup>7</sup>



Always visit the STERRAD Sterility Guide for the most updated information on instrument validations.<sup>9</sup>

## References

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