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India’s health services has banned reuse of single-use medical devices. But who decides what’s safe?

Unsafe reuse can harm patients, and billing for a reused device as if it were new is indefensible. But there is a bigger question that needs answering: who decides whether a device can be safely reprocessed, and on what evidence?

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India should make more of its expensive medical devices at home and fund independent Indian studies on their safety, performance and value for money. | Photo Credit: unoL

I still remember the stapler.

I was at Asan Medical Center in Seoul, watching liver transplants at one of the best programmes in the world, just as my own transplant career was beginning. The surgeon fired an expensive surgical stapler, finished the job and threw the device away. I was astonished.

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Back home in India, we often used the same stapler again and again, until we felt it was no longer safe. It was so expensive that our patients could afford it only if the cost was shared among many of them.

That memory came back when the Directorate General of Health Services (DGHS) issued its directive of October 16, 2026 that bans the reuse of devices labelled for single use in all public and private healthcare facilities. The concerns it cites include the risk of infection, possible breaches of existing laws, and cases where patients or government schemes were reportedly charged the full price for reused devices.

These are fair concerns. Unsafe reuse can harm patients, and billing for a reused device as if it were new is indefensible. But there is a bigger question: who decides whether a device can be safely reprocessed, and on what evidence?

Think about rockets. For decades, they were thrown away after a single flight. Then Elon Musk's SpaceX built boosters that could land, be checked and fly again, and spaceflight became much cheaper. If rockets can be reused, why not medical devices?

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Who decides what is single-use?

In two 2018 *Heart Asia* editorials, Thomas Crawford, Kim Eagle and colleagues point out that the single-use label is usually decided by the manufacturer, not by an independent regulator who has checked whether it could be safely reused.

A manufacturer that sells a single-use device earns money from every new purchase. Testing a device for reuse is expensive, and the single-use label avoids that cost. Every device thrown away is also a new sale. That said, manufacturers often have good reasons to limit use. Many devices have narrow tubes, fine hinges and delicate coatings that are hard to clean and check properly.

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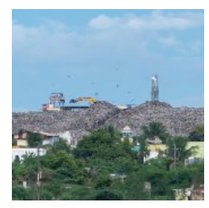
India's uncomfortable record

The truth about device reuse in India is not flattering. For years, hospitals have reprocessed devices without consistent protocols, proper tracking or any systematic record of outcomes. Our record on pricing is just as troubling. In 2017, Maharashtra's Food and Drug Administration reportedly investigated eight private hospitals over the reuse of 1,306 catheters across more than 1,000 patients. Reports also said patients were charged a large part of the maximum retail price for reused balloon catheters.

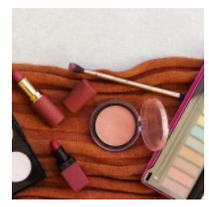
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What regulated reuse looks like?

Reprocessing is more than sterilising. A device can be sterile and still be weakened, unreliable or contaminated in ways the cleaning method does not reach. Depending on the device and the rules that apply to it, a reprocessor has to show that cleaning and sterilisation work, that the device still performs as it should, and that the whole process meets quality and reporting standards.

In the United States, the Food and Drug Administration treats anyone who reprocesses a single-use device as a manufacturer, with the same regulatory duties. Canada, Japan and the European Union have also set up rules for reprocessing, although the details differ from country to country.

Crawford and Eagle have suggested several ideas that India could use: clear labels on reprocessed devices, tested limits on how many times a device can be reused, tracking of each device, compulsory reporting of failures, independent oversight, and openness about the savings passed on to patients.

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Ban the abuse; build the system

The ban answers a real patient-safety concern. But a ban alone is not a plan to keep treatment affordable. Surgeons and other doctors have warned about the cost of a blanket ban, and these worries deserve a serious answer. They should not be used to brush aside safety risks, but the cost to patients should not be ignored either.

A national programme could sort devices into three groups: those that must never be reprocessed; those that could be reprocessed under tested and regulated conditions; and those where we do not yet have enough evidence and need more research. Any reprocessing that is allowed should happen only in approved facilities, with tested methods, a recorded limit on reuse cycles, and a way to trace each device. Failures and complications should be reported, and independent audits should check that the rules are followed. Where reprocessing is allowed, patients should be told clearly whether a device is new or reprocessed.

Finally, India should make more of its expensive medical devices at home and fund independent Indian studies on their safety, performance and value for money. We need affordable alternatives so that cost does not push anyone towards unsafe practices.

I keep coming back to the stapler I saw thrown away in Seoul. At the time, I watched a costly device go into the bin and wondered whether we could ever afford to do the same in India.

The rocket in Texas and the stapler in Seoul raise the same question: how do you make something expensive affordable without losing performance? In healthcare, this translates to: how do we make modern health practices both safe and affordable?

Throwing everything away is one answer. Making reuse safe is another. The difference between waste and progress is not whether we are willing to reuse. It is the evidence, the engineering and the accountability that make reuse safe.

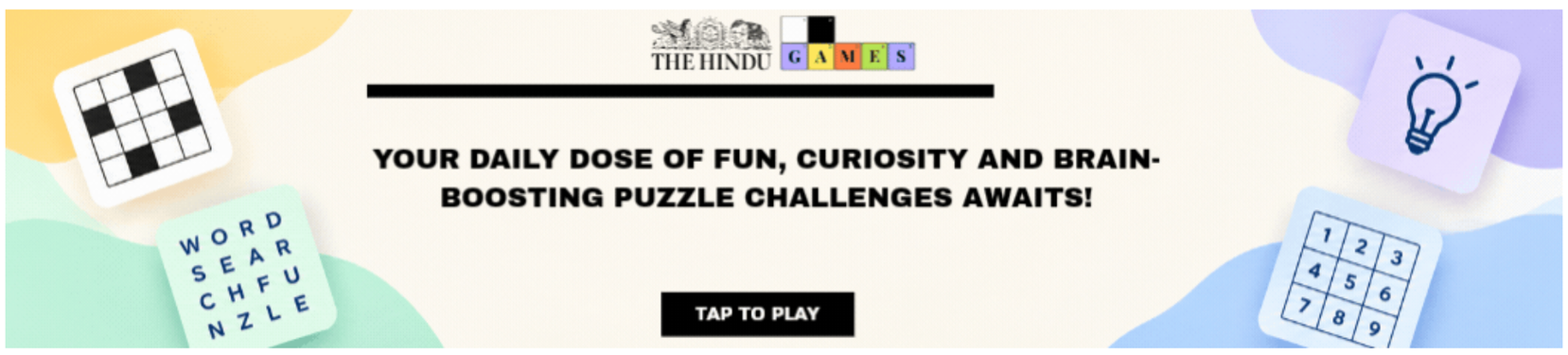
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